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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

19900 MacArthur Blvd., Ste 300
Irvine, California 92715-2445
Telephone (714) 798-7600

HAND DELIVERED

WARNING LETTER

WL-7-7

December 3, 1996

Gary B. Krantz
President
Diagnostic Solutions, Inc.
9 Pasteur, Suite 100
Irvine, CA 92718

Dear Mr. Krantz:

FDA inspections of Diagnostic Solutions, Inc., (DSI), Irvine, CA, have determined that your firm manufactures the Quick Check One Blood Glucose Test Strips, which are devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (Act).

FDA preliminary analysis of 14 lots of "QUICK CHECK ONE BLOOD GLUCOSE TEST STRIPS," lot numbers 16089A, 16136A, 16160B, 16180B, 16189B, 16190B, 16193A, 16196B, 16198A, 16202A, 16205B, 16208B, 16211B, and 16238A collected from two distributors, one located in New York and the other in Minnesota, determined that the devices are adulterated within the meaning of section 501(c) of the Act, in that their strength, purity, or quality falls below that which they purport or are represented to possess. The devices do not meet the performance claims established in the package insert and show and unacceptable meter-to-meter variance. Additionally, many of the lots also failed their release specifications and/or had results which were significantly different from the YSI by more than 20%.

The Center For Devices and Radiological Health (CDRH) has completed a review and evaluation of the current labeling against information previously submitted in premarket notifications under section 510(k), for the "QUICK CHECK ONE BLOOD GLUCOSE TEST STRIPS." CDRH has concluded that your firm has significantly changed or modified the device by changing the amount of active ingredients used in the reagent formulation.

Therefore, the "QUICK CHECK BLOOD GLUCOSE TEST STRIPS" are adulterated within the meaning of section 501(f)(1)(B), in that they are Class III devices under section 513(f) and do not have an approved application for premarket approval in effect pursuant to section 515(a), or an approved application for investigational device exemption under section 520(g).

These devices are misbranded within the meaning of section 502(o) in that a notice or other information respecting the modification to the devices was not provided to FDA as required Title 21, Code of Federal Regulations (CFR), section 807.81(a)(3)(i).

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence to each requirement of the Act and regulations. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. In accordance with the Federal Food, Drug, and Cosmetic Act, it is unlawful to ship an adulterated or misbranded device. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. Such action includes, but is not limited to seizure, injunction, and/or civil penalties.

Please notify this office in within five (5) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations.

Your reply should be addressed to:

Dannie E. Rowland
Compliance Officer
U.S. Food and Drug Administration
19900 MacArthur Boulevard
Irvine, California 92612-2445

Sincerely,

Elaine C. Messa
District Director
Los Angeles District

cc: State Department of Public Health
Environmental Health Services
ATTN: Chief, Food and Drug Branch
714 "P" Street, Room 440
Sacramento, CA 95814